Review of self-reported instruments that measure sleep dysfunction in patients suffering from temporomandibular disorders and/or orofacial pain

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Abstract: Patients with temporomandibular disorders (TMD) and/or orofacial pain (OFP) frequently experience poor sleep quality or suffer from comorbid sleep disorders. Study results suggest that in chronic pain patients, an improvement in sleep quality critically influences the outcomes of interventions on mood and pain. Yet, only a few studies have systematically sought to evaluate the sleep quality of TMD/OFP patients. Standardized and validated self-reported instruments designed for screening sleep disturbances or for the evaluation of treatment outcomes in this population would therefore enhance evidence and improve treatment options. The objectives of the present study were: (1) to review the self-reported instruments that measure sleep dysfunction in studies on TMD/OFP patients, by conducting a systematic literature search; (2) to evaluate their clinimetric evidence; and (3) to provide guidance for future research using such instruments. A total of 26 papers, using eight different instruments, were identified. The most frequently used questionnaires and the only ones with good clinimetric properties were the Insomnia Severity Index followed by the Pittsburgh Sleep Quality Index and the Epworth Sleepiness Scale. They were most reliable, valid and time-effective for measuring sleep dysfunctions in patients with TMD/OFP, with only a few practical constraints. Yet, in future studies, an assessment of the relationship between sleep disturbances and chronic pain will have to include instruments measuring the effect of mediator variables such as cognitive or emotional arousal. Research is required to clarify if existing self-reported questionnaires measuring these aspects will promote further insights or if there is a need for new instruments. This future research direction would blend into the overall biopsychosocial concept of TMD/OFP diagnoses and treatment.

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Review of self-reported instruments measuring sleep dysfunction in patients suffering from temporomandibular disorders and/or orofacial pain

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Abstract

Patients with temporomandibular disorders (TMD) and/or orofacial pain (OFP) frequently experience poor sleep quality or suffer from comorbid sleep disorders. Study results suggest that in chronic pain patients, improvement of sleep quality critically influences outcomes of interventions on mood and pain. Yet, only few studies have systematically sought to evaluate the sleep quality of TMD/OFP patients. Standardized and validated self-reported instruments designed for screening sleep disturbances or for the evaluation of treatment outcomes in this population would therefore enhance evidence and improve treatment options. Objectives of the study were 1) to review self-reported instruments measuring sleep dysfunction in studies on TMD/OFP patients by conducting a systematic

literature search, 2) to evaluate their clinimetric evidence and 3) to provide guidance for future research using such instruments. 26 papers using 8 different instruments were identified. The most frequently used questionnaires and the only ones with good clinimetric properties were the Insomnia Severity Index followed by the Pittsburgh Sleep Quality Index and the Epworth Sleepiness Scale. .They were most reliable, valid and time-effective for measuring sleep dysfunctions in patients with TMD/OFP with only few practical constraints. Yet, in future studies, an assessment of the relationship between sleep disturbances and chronic pain will have to include instruments measuring the effect of mediator variables like e.g. cognitive or emotional arousal. Research is needed to clarify if existing self-reported questionnaires measuring these aspects will promote further insights or if there is a need for new instruments. This future research direction would blend into the overall biopsychosocial concept of TMD/OFP diagnoses and treatment.

Key Words: temporomandibular disorders, orofacial pain, sleep quality, systematic literature search, Pittsburgh Sleep Quality Index, Insomnia Severity Index, Epworth Sleepiness Scale, self-reported questionnaires

Introduction

Orofacial pain (OFP) is part of the MESH[1] term “facial pain” which is defined in PUBMED[1] as “pain in the facial region including orofacial pain and craniofacial pain. Associated conditions include local inflammatory and neoplastic disorders and neuralgic syndromes involving the trigeminal, facial, and glossopharyngeal nerves. Conditions which feature recurrent or persistent facial pain as the primary manifestation of disease are referred to as facial pain syndromes”. OFP may more specifically be defined as pain and dysfunction primarily affecting the second and third division of the trigeminal nerve system. The prevalence of OFP in the general population is approximately 13% (range 1 to 48%) and has a greater prevalence among women [58,90]. The primary location of the pain has led to the

[1] MEDLINE (Medical Literature Analysis and Retrieval System Online) is the U.S. National Library of Medicine’s (NLM) premier bibliographic database that contains approximately 13 million references to journal articles in life sciences with a concentration on biomedicine. PubMed is a platform used to access bibliographic information that includes MEDLINE and OLDMEDLINE as well as other databases. MESH (Medical Subject Headings) is the NLM controlled vocabulary thesaurus used for indexing articles for Pubmed.

establishment of OFP as a discipline in the field of dental medicine [47]. Chronic OFP is most commonly associated with temporomandibular disorders (TMD) [87].

TMD is a collective term that embraces a number of clinical problems involving the masticatory muscles, the temporomandibular joints, and associated structures. Besides OFP, clinical manifestations of TMD may include limitation in jaw movements, and/or joint noises [3,65]. The aetiology and underlying pathogenetic mechanisms of TMD are still not fully understood. Genetic predisposition, trauma, bruxism, peripheral neural mechanisms, central pain processing, psychosocial and other factors are commonly considered to be involved [3,31,54,97,106]. As for OFP, a greater prevalence of TMD in women was observed [3,44,87], associated with greater pain and a different age distribution of prevalence of TMD than male patients [7,93].

TMD/OFP share features and are often associated with other chronic pain conditions (e.g. tension headache, fibromyalgia, chronic fatigue syndrome, irritable bowel syndrome) that are characterized by neuroendocrine abnormalities, frequent biopsychosocial distress and complaints, including fatigue, sleep disturbances, anxiety, and depression [29,36,55,68,70,80,102,106,116].

The variation in sleep between species and during their lifespan suggests that sleep may have many functions and thus generating a sleep definition is a daunting task [34,42]. Still, sleep disturbances impair quality of life and are one of the most widespread comorbid conditions in chronic pain patients [53,55,70,75,78]. The prevalence of sleep-related disturbances in clinical samples of chronic pain patients is typically greater than in the general population and is often reported in the 50-70% range or higher [53,60,78,87]. Pain may be associated with sleep instability, disruption of non-REM to REM sleep cycles continuity and excessive sleep fragmentation [53], which may in turn increases the perception of unrefreshing or nonrestorative sleep (NRS). NRS refers to the subjective experience of sleep as insufficiently refreshing or to the feeling that sleep is restless, light, or of poor quality even though traditionally assessed objective sleep parameters (e.g., total duration, sleep stage distribution) appear normal [74,75]. Differential etiological causes for NRS and insomnia symptoms, like difficulty initiating or maintaining sleep, are discussed [76].

Pain associated sleep arousals and/or other markers of sleep discontinuity (e.g. sleep-related movement arousals, respiratory related arousals) identified either by self-report or by polysomnography (PSG) may impair sleep quality. Reciprocally, insufficient sleep (namely sleep

deprivation) or poor sleep quality may induce pain hypersensitivity, exacerbate pain responses, and alter mood states without clearly understood pathomechanisms [50,53,89,95].

It was demonstrated that insomnias associated with chronic pain are often phenotypically similar to primary insomnia [105]. Insomnia is defined as a complaint of prolonged sleep latency, difficulties in maintaining sleep or the experience of nonrefreshing or poor sleep, which have to be coupled with impairments in daytime functioning such as lack of concentration, dysphoria, fatigue and other symptoms [86,52]. Similarly, the most common sleep-related complaints of pain patients are delayed sleep onset, restless sleep, frequent awakenings, and NRS [25,70,87]. It has been suggested that the primary impairment is in the perception of sleep quality, rather than in real sleep performance per se, particularly for patients with high levels of pain [87]. The relationship between pain and poor sleep is often assumed as bidirectional (poor sleep exacerbates pain, while greater pain adversely affects sleep [78]). This model was challenged by the results of Tang et al., indicating that presleep pain was not a reliable predictor of subsequent sleep in a heterogeneous sample of 119 chronic pain patients with concomitant insomnia. Instead, sleep efficiency and quality are best predicted by the presence of presleep cognitive arousal, while on the other hand, sleep quality was a consistent predictor of pain [110].

Only few studies have systematically sought to evaluate sleep quality and sleep disturbances of TMD/OFP patients [83,106,116], although 60% of OFP patients responded affirmatively on a question about sleep disturbance. Further, 77% of a cohort of OFP patients reported a reduction of their sleep quality since the onset of their pain and investigations consistently found that over 50% of TMD patients report poor sleep quality [55,87,106]. In their comprehensive PSG study of sleep in a well characterized sample of myofascial TMD patients, Smith et al. diagnosed high rates of different sleep disorders [106]: 75% met self-report criteria for sleep bruxism (SB), 17% met PSG criteria for SB, 36% met criteria for insomnia and 28.4% were diagnosed with sleep apnea syndrome (SAS). Primary insomnia (PI) comprised the largest subcategory of insomnia (26%), while psychophysiologic insomnia (PPI; 20.8%) comprised the largest subcategory of PI.

In summary, it may be said, that there are similarities between populations of TMD/OFP and other chronic pain patients concerning the higher prevalence of the female sex and the prevalence of sleep disturbances, while SB and SAS are more frequent in TMD/OFP.

The aim of this comprehensive review was to 1) review self-reported instruments measuring sleep dysfunction in studies on TMD/OFP patients, 2) evaluate their clinimetric evidence and 3) provide guidance for future research using such instruments.

Methods

A systematic literature search was conducted in March 2013 and updated in August 2013 in three literature databases (PUBMED, EMBASE[2], and PsycInfo[3]) to identify articles using instruments measuring sleep disturbances in populations of TMD/OFP patients. The search was limited to human adult papers published in English between 2002 and 2013. Only full-text articles targeting on outcome measures were selected. The comprehensive search strategy used the following terms and their variants: (sleep[title/abstract]) and (instrument) or (assessment) or (questionnaire) or (interview) or (diary) and (TMD[title/abstract]) or (temporomandibular[title/abstract]) or (orofacial pain[title/abstract]). The search results were supplemented by hand searching relevant journals from 2002 to present and reference lists with regards to included and excluded studies. Figure 1 shows the literature search strategy with its different steps and criteria for inclusion or exclusion of papers.

Results

Number of studies found

A total of 26 articles focusing on patients with TMD and/or OFP were found that included an instrument measuring sleep disturbances. They contained 8 different instruments. The most frequently used type of instrument were questionnaires, among which the Pittsburgh Sleep Quality Index (PSQI; 15/26 papers) was most commonly applied, followed by the Epworth Sleepiness Scale (ESS: 5/26 papers). Only one study used an interview. None of the studies employed sleep diaries. For more details see Table 1.

[2] Comprehensive index of world literature on human medicine and related disciplines, contains 15 million records drawn from the international literature.
[3] PsycInfo contains abstracts of articles from about 1200 journals on psychology topics.

Purposes and aims of the various sleep measures used in studies on TMD/OFP

The choice of instrument measuring sleep disturbances and related consequence depended on the type or symptoms the studies focused on: The PSQI and the Sleep Assessment Questionnaire (SAQ) were used to measure patient-reported sleep quality, independent of the type of sleep disorder. In two cases, the PSQI-total score was used to distinguish between poor and good sleepers [106,116]. Rai and Kaur [82] additionally used the PSQI to measure the number of hours spent in bed, the number and reasons of awakenings and difficulty returning to sleep. Two further studies only used one PSQI subscale (#1 or #6) to assess sleep quality [2,91]. The ESS was used for the assessment of excessive daytime sleepiness (EDS) in TMD/OFP patients [106] in TMD patients suffering from SAS [23,24,79] and/or SB [1]. In addition to the ESS, the Fletcher and Luckett Questionnaire was used to assess symptoms of SAS and EDS [24], while the Douglass Sleep Disorders Questionnaire (SDQ) was used for the diagnosis of SAS only [23]. The Insomnia Severity Index (ISI) was used to measure insomnia severity [81,104,106]. The Jenkins Sleep Problems Scale (JSPS) was used to build sleep disturbance scores [5]. In one study a modified version of the Structured Interview for Sleep Disorders (SIS-D) was administered to diagnose DSM Axis-I and Axis-III sleep disorders based on DSM-IV revisions [106]. A single study used a battery of four measures to quantify sleep quality and daytime symptoms associated with sleep disorders but the purpose of each instrument was not declared [106].

General description and clinimetric evaluation of the sleep instruments found

For all instruments presented in this systematic review, validity studies are currently lacking in patients suffering from TMD/OFP. Importantly however, their primary clinimetric focus is sleep dysfunction independent of comorbidities (e.g. various types of pain, metabolic disorders, cancer, diverse psychiatric disorders, etc.). To confirm that these instruments truly measure what they claim, validity studies were additionally performed in patients with sleep disturbances as a secondary complaint. Notably, across the instruments presented, evidence for their clinimetric properties varies, as presented in Table 2.

The PSQI [13] is an 18-item commonly employed self-report questionnaire that assesses general sleep quality. It is not specific for any single primary sleep disorder. It has been widely translated and

employed in a wide range of populations-based and clinical studies [67]. It provides information on the number of hours of sleep, the number of awakenings during sleep, sleep latency, sleep efficiency, and use of sleep medication. The PSQI has been shown to be a valid and reliable instrument for assessment of overall sleep quality and disturbance, with good test-retest reliability and internal consistency [6]. The questionnaire is easy to handle and can be completed within 5-10 min. For more details see Table 2.

The ESS was developed by Johns (1991) [47]. It was designed to quickly and conveniently measure daytime sleep propensity in populations suffering from a variety of sleep disorders. The scale comprises eight items that address typical day-to-day situations and respondents are asked to rate their likelihood of dozing in each situation. The ESS is a very popular research and clinical tool and is available in several languages. The ESS has good internal consistency and reliability [21,35,48,104] and has been compared to external criteria including the multiple sleep latency test (MSLT) and maintenance of wakefulness test (MWT) [104]. In a confirmatory factor analysis Smith, Oei et al. found that the original single-factor structure proposed by Johns did not adequately fit the data [104]. The authors therefore propose a re-specified single-factor solution for patients with obstructive sleep apnea. The questionnaire is easy to handle and can be completed within 5 min. For more details see Table 3.

The SAQ was developed to screen for primary sleep disorders and sleep abnormalities in epidemiologic studies [19,20]. It is a 17 item self-administered questionnaire. The items are scored on a 5 point Likert scale from 1 (never) to 5 (always). Factor analysis of the 17 items has identified six sleep factors: insomnia; NRS; restlessness; daytime sleepiness; sleep apnea and sleep schedule disorder. Receiver Operating Curves (ROC's) have been calculated for the total SAQ score as well as for the factor scores (with exception of the sleep schedule disorder factor) to show the sensitivity/specificity at various cut-offs. It has been shown to be a highly sensitive and specific measure capable of discriminating between patients with different sleep disorders and between patients with sleep disorders and controls free of sleep disturbances [64,66,111]. For more details see table 2.

The ISI is a brief instrument designed to assess the severity of both nighttime and daytime components of insomnia [8]. It is available in several languages and is increasingly used as a metric of treatment response in clinical research. It offers good clinimetric properties [71,98]. Its seven items correspond partly to DSM-IV criteria for insomnia [8], but perfectly to DSM-V criteria[4] and measure current perception of insomnia symptom severity, distress and daytime impairment. Each of these items is rated on a five-point Likert scale. Total scores range from 0 to 28, with high scores indicating greater insomnia severity. A cutoff score of 10 was optimal for detecting insomnia cases in the community sample [70]. The ISI is available in three different versions: patient (self-administered), significant others (usually a spouse) and clinician [8]. The questionnaire is easy to handle and can be completed within 5 min. For more details see Table 2.

The SDQ [27] was designed as a tool for identifying persons at high risk for a sleep disorder. The 175-item scale was created by selecting the best and most salient questions from the Sleep Questionnaire and Assessment of Wakefulness (SQAW), a general measure consisting of more than 800 items [99]. The scale was initially intended for general practitioners and other professionals outside the field of sleep medicine. The developers also created a smaller, 45-item version of the scale to assess four common sleep disorders: sleep apnea, narcolepsy, psychiatric sleep disorders, and periodic limb movement disorder. Good clinimetric qualities were found for the 45-item version [27]. For more details see table 3.

The Fletcher and Luckett questionnaire[5] [32] consists of 25 questions about sleep, snoring nocturnal apnea, and daytime somnolence. The original purpose of the questionnaire was to determine the level of baseline OSA symptoms in a population of 20 OSA patients actively using nCPAP for 6 months to 2 years. To achieve this, the total score was divided by 25. No data concerning the clinimetric evaluation is available (see Table 3).

The JSPS [46] was designed as an efficient and brief instrument for use in research. The four items evaluate the frequency and intensity of sleep disturbances on a five-point Likert scale. Though the questionnaire is short, the authors suggest that it has been shown to possess good predictive value in

[4] personal information by Prof. Charles Morin, Université Laval, Québec, Canada (2014)
[5] No shortname published

previous studies [46]. With only four items it cannot address the entire spectrum of sleep disorders and is thus to be considered as a preliminary screening device [46]. The average time for administration is 2-5 min. For more details see Table 2.

The SIS-D [94] is a structured clinical interview that can be used by experienced psychiatric interviewers to assess sleep-wake disorders. Adequate administration requires training and careful study of the instruction manual. The interview consists of a brief semistructured overview containing questions about physical health, use of medication, use of drugs, use of alcohol, and history of mental illness as well as some more specific screening questions on sleep apnea and narcolepsy, a structured section systematically inquiring about specific symptoms of sleep disorders, and a summary score sheet to be filled in by the rater after completion of the interview. All axis I diagnoses (according to DSM-III-R) can be evaluated as current or lifetime. Axis III diagnoses (according to DSM-III-R) are evaluated only as current and are considered provisional until confirmed by sleep laboratory findings. The instructions for the SIS-D permit the interviewer to omit irrelevant sections and proceed to the next one. The average time for administration is 20-30 minutes [94]. It is the only published interview that demonstrates sound reliability and validity based on PSG and expert interviews [106]. For more details see table 2.

To provide information about the frequency of utilization in scientific publications on sleep disturbances, a brief Pubmed search was performed in May 2013 for each instrument, using the short- and full name of the measure in quotation marks as search criteria (only adults). As shown in Figure 2, the number of citations varies in a great amount between the most frequently used (ESS, PSQI) and the rarely used measures. Comparing the number of citations, Figure 2 shows that the ISI is the most frequently used questionnaire for chronic pain patients (9 citations out of a total of 43, i.e. 21%) and also for TMD/OFP patients (3 citations of out of a total of 43, i.e. 7%), followed by the PSQI (55 and 15 of 633, i.e. 9% and 2% for chronic pain and TMD/OFP respectively), while only 3% (21 of 787) of the studies using the ESS focused on chronic pain and TMD/OFP patients. The result that the SAQ returned less general citations than uses with TMD/OFP patients is due to the search strategy applied. The frequency of use of the instruments in TMD/OFP populations did not reflect the number of general citations, with rarely cited instruments being overrepresented in the present study.

Overview of the results obtained in the studies using the PSQI, the ISI and/or the ESS

In summary, the three most frequently used questionnaires in this study demonstrated their clinimetric properties and limitations in intervention, longitudinal and correlative designs. A summary of the results obtained by the use of these instruments, as discussed by the authors of the respective studies, follows below, ordered by clinimetric properties:

1- *Sensitivity to change*

In 4 cases the *PSQI* was used in intervention studies. In 2 of these cases it was shown that different types of psychological pain treatment (hypnosis or relaxation) decreased PSQI scores in intervals of 5 or 4 weeks, respectively [2,3]. Yet, the sensitivity to change of the PSQI was not thoroughly demonstrated, since a control group receiving no treatment at all is missing in both studies. In 1 of these cases sleep quality was positively associated with self-care behavior like relaxation, application of hot/cold packs and performing stretching exercises [88]. On the other hand, pharmacological treatment (clonazepam or cyclobenzaprine) applied over a three weeks interval failed to improve sleep quality [41].

In 1 case the *ISI* was used in a longitudinal study over 12 weeks. This case showed that increases in either insomnia symptoms or usual pain ratings in the initial month were associated with next-month decreases in these constructs, respectively. Additionally the authors also observed a significant association between initial-month changes in insomnia symptom severity and next-month increases in clinical pain, even controlling for prior changes in pain and concurrent changes in insomnia. According to the authors, these data suggest that naturally occurring fluctuations in insomnia symptom severity are prospectively associated with fluctuations in daily pain experience for persons with TMD/OFP [81].

In 1 case the *ESS* was used in an intervention study which showed that Mandibular Advancement Device (MAD) therapy did not influence ESS total scores [24]. According to the authors, this result may not be generalized because no objective measures of EDS were applied.

2- *Discrimination capacity between subgroups of TMD/OFP patients or between TMD/OFP patients and healthy controls*

In 7 cases *PSQI total scores* were used to discriminate between groups and showed that total scores were higher in TMD/OFP patients

- with Posttraumatic Stress Disorder Syndrome (PTSD) symptoms compared to TMD/OFP patients without PTSD symptoms [9,55]
- compared to healthy controls [56,57]
- in the myofacial pain (MP) subgroup compared to the intracapsular pain (IC) subgroup and
- compared to patients with chronic daily headache (CDH; [114]),while
- no differences in PSQI total scores were found in TMD patients with neuropathic compared to myofacial pain [80]
- and also no differences in PSQI total scores were found in crew members reporting either TMD symptoms or simple muscle pain or nothing after being exposed during 6 days to a simulated mars mission [82].

In 2 cases *PSQI cutoff scores* (< 5 and < 10, respectively) helped to discriminate between poor and good sleepers in TMD/OFP populations [106,116].

In 1 case the ISI was used to discriminate between poor and good sleepers in TMD/OFP population and it was shown that *ISI total scores* were significantly higher in TMD/OFP patients presenting a high burden of suffering (PRISM-inself patients) compared to TMD/OFP patients presenting a low burden of suffering (PRISM-outself patients) [108].

In 1 case the *ESS cutoff value* >10 was used to define the presence of EDS. It was shown that 19% of the TMD/OFP patients suffered from EDS compared to 10% in the healthy group [23].
In 2 cases, *ESS total scores* were used to discriminate between groups, showing

- slightly, but significantly higher values in TMD/OFP patients suffering from SB than in healthy controls [1]
- significantly higher ESS total scores in TMD/OFP patients defined as poor sleepers than TMD/OFP patients defined as good sleepers [106].

3- Analysis with Correlation

In 1 case *PSQI total scores* were used to test a mediator hypothesis and it was shown that PTSD symptoms exert their influence on OFP through depression and sleep quality [12]. In the last of the total of 15 cases, poor self-rated sleep quality (PSQI item #6) was a putative predictor of first-onset TMD in people with a high likelihood for OSA [91].

In 1 case the *ISI* was probably used to diagnose insomnia – in addition to PSG – but an exact description concerning the contribution of the ISI to the diagnostic process has not been reported [106].

In 1 case the decrease in *ESS total scores* and in other OSA symptoms of TMD/OFP free and TMD/OFP patients, both suffering from OSA, were used to determine the length of the titration period of MAD [79].

Discussion

To further the understanding of the comorbidities of TMD/OFP and sleep disturbances, researchers and clinicians require cost and time effective, standardized and validated instruments for screening and for evaluating treatment outcomes. Selecting the 'best' instrument for clinical practice involves careful consideration of an instrument's ability to screen, diagnose and/or monitor sleep disorders, poor sleep quality and resulting daytime impairment [22]. The aim of our study thus was to identify existing self-report instruments measuring sleep dysfunction in cohorts of TMD/OFP patients, to evaluate the strength of their clinimetric evidences and to provide guidance for research and clinical practice.

General remarks on clinimetric evidences

Instruments measuring sleep dysfunction aim at assessing sleep parameters independent of somatic or psychiatric comorbidities. Once the validity and reliability (i.e. clinimetric evidence) of an instrument has been sufficiently demonstrated in a variety of ambulatory and/or clinical settings, its use can be expanded to any populations where measurements of sleep dysfunction are of interest. A key finding of this review is that clinimetric soundness substantially varies across the instruments identified, as evidenced by 1) reliability scores (e.g. Crohnbach's alpha), 2) available information concerning content

and/or criterion validity, 3) available sensitivity and specificity values, and 4) published information on sensitivity to change (Tables 2 and 3). The clinimetric soundness is strongest for PSQI, ISI, ESS, and to certain extent to SDQ, intermediate for SIS-D, and lowest for SAQ, JSPS, and Fletcher and Luckett sleep questionnaire (Table 4).

The question arises if sleep dysfunction in pain patients, specifically suffering from TMD/OFP, differs from other patient populations. As of today, no publication identified a specific pain related sleep dysfunction that would not be found in other populations. Rather, the most common sleep related complaints of pain patients are phenotypically similar to primary sleep dysfunctions, e.g. insomnia [25, 70, 87, 105]. Therefore, instruments with strong clinimetric properties do not require further testing in TMD/OFP patients.

General comparison of instruments measuring sleep dysfunction

Measurement targets determine which type of instrument is best utilized to address a specific clinical or research question. *Sleep questionnaires* are good and cost-effective instruments for the purpose of screening for sleep disturbances, for the assessment of subjective sleep quality and for the monitoring of treatment course and outcome [22,30,33,72]. *Sleep interviews* on the other hand provide more complex information, allow more valid diagnoses compared to questionnaires [94] and offer – especially in the semi-structured version – a better relationship with patients. Their disadvantages include longer time for administration and often the need for specific training for administration, scoring and interpretation. Since high agreement between results based on interviews and questionnaires has been found for chronic headache [38] and for sleep problems [30] the decision to use an interview requires careful consideration. *Sleep diaries* are useful for sleep assessment and tracking treatment effects [16]. They permit the evaluation of intraindividual variability across a study period which is particularly advantageous when combined with daily pain ratings (e.g. [73]). Sleep diaries can be specifically designed and customized as paper-and-pencil or electronic versions (e.g. [110]). Yet, as stated by Buysse et al. in their recommendations for a standard research assessment of insomnia, the collective impact of sleep diary studies has been limited by a lack of standardization [15]. This contributed to inconsistencies in study findings and has compromised the ability to fully interpret and integrate results of previous studies [69]. There is agreement that sleep diaries should yield information about relevant metrics including sleep onset latency (SOL), wakefulness after initial sleep

onset (WASO), total sleep time (TST), total time spent in bed (TIB), sleep efficiency (SE = TST/TIB*100%), and sleep quality or satisfaction as a subjective global appraisal of each night's sleep. On the other hand, there is no agreement on the format of the sleep diary [16], what lead to multiple lab-specific versions as mentioned above. The Consensus Sleep Diary (CSD) developed by Carney et al. was the result of collaborations with insomnia experts and potential users [16]. Other sleep diaries, like the Karolinska Sleep Diary (KSD) and the Pittsburgh Sleep Diary (PSD) are examples described in Devine et al. [26].

Although for each category of the before mentioned self-reported instruments, examples with sound clinimetric properties do exist, their use for diagnostic purposes in sleep medicine is limited. Gold standard for the diagnosis of SAS and SB is *laboratory or home recording PSG.* The latter has major advantages since patients are in their natural sleep milieu [4,59]. PSG for diagnosing SB is superior to clinical examination since none of the clinical signs constitute direct proof of current SB activity [17,60]. For SB contradicting findings have been published based on self-report versus those based on PSG, including masticatory muscle electromyography (EMG) and/or audio-video recordings [61,62,106]. The lack of internal validity of self-reported SB diagnosis is due to the fact that the self-reported assessments are mostly based on only one or two items of insufficient homogeneity [63]. This may sound surprising, since validated questionnaires for the assessment of SB do exist in research milieu; this raises another issue: can a questionnaire designed for mechanistic research studies (i.e., screening subjects with high likelihood of tooth grinding) be directly used in general population without further validation. [60,113]. The use of SB questionnaires may be a good alternative to collect objective measures such as EMG or PSG in large groups of patients. However, self-report measures of SB and other oral parafunctions have been criticized for the possibility that patients are unable to observe and report their own activities accurately and further support need for more specific questions assessing the disorder of interest with possible co-morbidities [112].

PSG is not a common tool to assess insomnia. The most common instrument to address this issue is *actigraphy*. Combined with sleep diaries, it is considered the gold standard for the diagnosis of insomnia and may contribute decrypting the source of variation and predictive variables in pain and sleep interaction [14,110]. Although actigraphy/PSG is a simple and a more practical tool, users have to recognize some of its limitations such as the lower estimation value for sleep efficiency in specific population with poor sleep and/or sleep disturbances [109]. In conclusion for this section, subjective

sleep complaints often do not match objective measurement of sleep by PSG or actigraphy, a robust finding thoroughly addressed by Tang et al. [110], which is particularly true for pain patients [78,110]. Thus the choice of an instrument primarily depends on the interest of the researcher or clinician to collect either objective or subjective data concerning sleep.

One or several instruments?

Clinicians and researchers face the challenge to decide on the number of instruments needed. As shown by Mondal et al., only limited associations exist between the PSQI and the ESS, although the authors expected the level of association between these two instruments to be high due to the characteristics of their study sample. They assessed patients referred to PSG by physicians trained in sleep medicine and expected this population to be at high risk for sleep disorders and consecutive daytime sleepiness [67]. But, as had to be expected, the two questionnaires evaluated different dimensions of sleep that were only related in a subgroup of patients with SAS. This example illustrates that the inclusion of instruments measuring different facets of sleep disturbances is recommended if the focus lies on global assessments of sleep disturbances.

Debate of the instruments used in the selected TMD/OFP studies

Questionnaires were the most common type of self-report instruments employed in eligible studies. Only one study used an interview and no study used a sleep diary. As stated before, the 8 instruments identified in the 26 studies that were evaluated differed substantially concerning their clinimetric evaluation (Table 4). This fact may also be reflected by the large variations in the number of citations (Figure 2). All questionnaires used were self-administered and easy to complete for patients. Scoring was simple and interpretation accessible in most studies.

According to the studies surveyed, insomnia, SAS and SB seem to be the most frequent types of sleep disorders, while poor sleep quality and excessive daytime sleepiness seem to be the most frequent complaints of TMD/OFP patients. Concerning insomnia symptoms, the most common sleep-related complaints of pain patients are delayed sleep onset, restless sleep, frequent awakenings, and NRS. Set apart the ISI, none of the 7 other instruments focused directly on these sleep problems. In

contrast, Cole et al. [22] recommend the use of the MOS Sleep Scale [40], namely because of its validated dimension and score for sleep disturbance. This subscale consists of 4 items asking for "trouble falling asleep", "sleep restlessness", "awaken during sleep" and "time to fall asleep". Furthermore, SB and its impact on sleep disturbances and sleep quality was not addressed by any of the instruments used. Although SB may not be related to TMD [61,84], a significant association between SB and insomnia was detected both in TMD and general population studies [60,106]. The debate on the association between sleep-related movement disorders, such as SB, and impaired sleep quality and/or insomnia remains to be tested with more specific questionnaires assessing pre-sleep cognitive and somatic arousal [65,105,110].

The SDQ and the Fletcher and Luckett Questionnaire were used to directly assess SAS, although instruments like the Berlin Questionnaire, the STOP and the STOP-Bang questionnaires are more frequently used and provide better clinimetric performance [4,99]. The ESS has a high validation for EDS but its diagnostic efficiency for SAS is inconclusive, since it only assesses a possible consequence of SAS [101,104].

Nevertheless, recommendations concerning the 'right' selection of questionnaires are problematic since the process of selecting questionnaires in studies on sleep disturbances has to involve considerations concerning the kind of study anticipated and the theory underlying the sleep disturbance being addressed [22,72]. In order to facilitate this selection process, the purpose of each instrument was listed in Tables 2 and 3 according to the conceptual framework of sleep dysfunction defined by Moul et al. [72].

Conclusions and future research

The validity of PSG for diagnosing sleep disturbances is undisputed (either in laboratory or home natural milieu). However, its utility is constrained by availability, patient inconvenience and cost. Sufficiently validated questionnaires on the other hand are easily administered and cost-effective information gathering tools that aid clinicians in their decision making process. As explained above, they do not need to be validated in TMD/OFP patients as long as their clinimetric properties are adequately established elsewhere. From a biomedical perspective, a short and practical questionnaire for TMD/OFP should include at least the following: sleep quality, insomnia symptoms (night and day), tooth grinding awareness, and sleep breathing disorders related items. Yet, future studies on the

relationship between sleep disturbances and chronic pain in patients with TMD/OFP will likely have to include mediator variables such as cognitive and emotional arousal [106,115]: As shown by Buenaver, the relationship between pain and sleep may be conceptualized as a network composed of direct and indirect pathways, with the rumination component of pain catastrophizing indirectly contributing to TMD pain through alterations in self-reported sleep [11]. Lautenbacher identified failures in problem solving (a cognitive dysfunction typically associated with depression) as a further possible indirect pathway [51]. The view on the different pathways linking together sleep and pain in TMD/OFP patients has thus to be expanded towards a *biopsychosocial framework* considering that cognitive (e.g. unwanted mental activity at bedtime which can take the form of verbal thought or visual imagery [39]) as well as affective factors (e.g. anger, irritability, catastrophizing [10,14,18,29,49,84,100]) play an important role in the sleep-pain network [105,110].

Considering the above, we conclude that reliance on a purely biomedical model of sleep disturbances and chronic pain might not fully account for all aspects of their inter-correlation or relationship. To date, little is known about the pathways linking cognitive and emotional arousal with chronic pain and sleep disturbances in patients suffering from TMD/OFP. In order to address these aspect adequately, there might be a need for the development of new instruments or existing instruments measuring cognitive and affective arousal might be used, such as e.g. the “Fragebogen zur Erfassung allgemeiner und spezifischer Persönlichkeitsmerkmale Schlafgestörter” (FEPS-II [43]) or the “Anxiety and Preoccupation about Sleep Questionnaire” (APSQ [45]) or instruments measuring attempts to control thoughts like the “Thought-Control Questionnaire Insomnia-Revised” (TCQI-R [84]). This future research direction would blend into the overall biopsychosocial concept of TMD/OFP diagnoses and treatment [28,77].

Conflicts of interest

The authors declare no direct conflicts of interest and no grant or salary support from an agency related to this paper at the exception of a governmental Canada Research Chair to GL.

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Figures and Tables Legend

Fig. 1

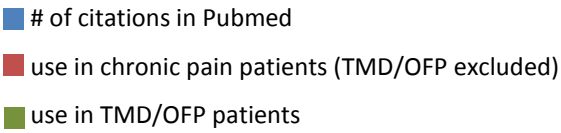
Title: Literature search strategy: Different steps and criteria for inclusion or exclusion of papers

Legend: none

Fig. 2

Title: Number of citations, number of studies on chronic paint patients (both May 2013) and number of studies on TMD/OFP patients using the sleep related measures

Legend:



FLQ = Fletcher and Luckett Questionnaire; other abbreviations, please refer to text.

Table 1

Title: Summary of instruments used for measuring sleep dysfunctions in TMD/OFP patients

Legend:

EDS = excessive daytime sleepiness; SAS = sleep apnea syndrome

Table 2

Title: Description of instruments primarily focusing on aspects of sleep quality and insomnia

Legend:

none

Table 3

Title: Description of instruments primarily focusing on aspects of excessive daytime sleepiness (EDS) and sleep apnea syndrome (SAS)

Legend:

EDS = excessive daytime sleepiness; SAS = sleep apnea syndrome

Table 4

Title: Summary and appreciation of the clinimetric soundness of the instruments found in this study

Legend:

Evaluation criteria for the critical appraisal

Reliability:

good = Cronbach´s alpha and/or test-retest reliability and/or item-total correlation > 0.8

Validity:

good = High correlation between the test and a criterion variable (or a gold standard) taken as representative of the construct (r > 0.8) and/or capacity to distinguish good from bad sleepers or normal controls from patients.

Sensitivity/Specificity:

excellent = sensitivity and specificity as close to 100% as possible and cut-off score published
good = sensitivity and specificity as close to 100% as possible, no cut-off score published

Sensitivity to change:

Sensitivity to change is unclearly defined. Two of the mostly used definitions are “the capacity of a measure to detect change in patients' status over time” or “the clinical meaningfulness of changes in scores” [107].

good = information available, independent of the definition chosen

Final appraisal:

good = Report of the results of validation was published and all criteria appraised as good
intermediate = Report of the results of validation incompletely published, but good reliability and validity
insufficient = Report to the results of validation incompletely published or unpublished